BARNES & THORNBURG LLP

11 South Meridian Street
Indianapolis, Indiana 46204
(317) 236-1313
(317) 231-7433 Fax

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Customer No.	23643
Group:	3761
Confirmation No.:	4275
Application No.:	10/664,535
Invention:	VACUUM THERAPY AND CLEANSING DRESSING FOR WOUNDS
Inventor:	Jeffrey S. Lockwood et al.
Filed:	September 19, 2003
Attorney Docket:	7175-73441
Examiner:	Bogart, Michael G.

ELECTRONICALLY SUBMITTED: OCTOBER 15, 2008

APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Appeal Brief is submitted in support of the appeal from the Primary Examiner's April 17, 2008 final rejection of claims 32, 38, and 40. This Appeal Brief has been filed in accordance with 37 C.F.R. § 41.37 within two months of the August 15, 2008 filing date of the Notice of Appeal. Please charge the $510 fee for filing the Appeal Brief to the Account of Barnes & Thornburg, Deposit Account No. 10-0435 with reference to file 7175-73441. It is

respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and that shortages in fees, if any, be charged, or any overpayment in fees credited, to the Account of Barnes & Thornburg, Deposit Account No. 10-0435 with reference to file 7175-73441.

REAL PARTIES IN INTEREST

The real party in interest in the present application is Hill-Rom Services, Inc., the assignee of the present application and any patents issuing from the present application via an assignment document recorded at the Patent and Trademark Office for U.S. Patent No. 6,685,681, of which the present application is a divisional, at reel 011503 and frame 0726. Hill-Rom, Inc. was a wholly-owned subsidiary of Hillenbrand Industries, Inc. which traded on the New York Stock Exchange (NYSE) under the ticker symbol HB. However, on March 31, 2008, Hillenbrand Industries, Inc. split into two separate publicly traded companies. Hillenbrand Industries, Inc. spun-off Batesville Holdings, Inc. (along with all of the wholly-owned subsidiaries of Batesville Holding, Inc.) and changed the name of Batesville Holdings, Inc. to Hillenbrand, Inc. which is now traded on the NYSE under the ticker symbol HI. At the time of separation, Hillenbrand Industries, Inc. changed its name to Hill-Rom Holdings, Inc. and now is traded on the NYSE under the ticker symbol HRC. HRC is the stock ticker symbol of the only publicly traded company that presently has an interest in the present application due to one of its subsidiaries being the owner. It is believed that the preceding provides the Board of Patent Appeals and Interferences with sufficient information to undertake its ethical conflict of interest analysis. However, if additional information is required, please contact the undersigned.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 32-35, 38, and 40 are pending in this application. Claims 32, 38, and 40 are rejected. Claims 33-35 are objected to. Each of claims 32, 38, and 40 is appealed.

A copy of claims 32, 38, and 40 currently under appeal is attached hereto in an Appendix.

STATUS OF AMENDMENTS

No amendments have been made to the claims subsequent to the April 17, 2008 rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

The invention may best be understood by referring to FIGS. 1-16 and the following copies of appealed claims 32, 38, and 40, annotated with parenthetic reference numbers and portions of related paragraphs from the specification of U.S. Patent Application Publication No. 2004/0064111 which corresponds to the present application, and any such reference and/or accompanying explanation:

> (i) is by way of example of the claimed subject matter only and is neither a comprehensive description of the scope of the independent claim being discussed nor a comprehensive listing of support in the specification for the independent claim being discussed;
>
> (ii) might be potentially useful in clarifying the particular subject matter of the particular independent claim being discussed (and not other claims or "the invention" as a whole), unless explicitly stated otherwise; and

(iii) is not to be considered as broadening or narrowing or otherwise affecting the interpretation of any claim or part of a claim, unless explicitly stated otherwise.

Additionally, any explanation or reference to the specification which refers to more than one claim, or is utilized in the explanation of more than one claim, is not to be considered as broadening or narrowing or otherwise affecting the interpretation of any claim or part of a claim, and is not to be considered as indicating any equivalence of any claim or parts of a claim.

32. A method of treating an open wound having a wound surface located inwardly of healthy skin surrounding the open wound, (See wound care bandage 10 for use with a vacuum source 12 and an irrigation source 14, as shown in FIG. 1. See wound dressing member 20 shown in FIGS. 2-16. See wound 16 shown in FIG. 3. See paragraph [0030], first sentence which states "[b]andage 10 promotes the healing of a large wound 16 (shown in FIGS. 3 and 7) by providing vacuum therapy to the wound 16 to promote blood flow and remove exudates from a wound surface 18 of the wound 16 and by providing for irrigation of the wound 16 with fluids such as saline, for example."), **the method comprising:**

providing a relatively thin and flexible member having a wound contacting surface with holes in the wound contacting surface (See wound dressing member 20 shown in FIGS. 2-16. See paragraph [0031], first sentence which states "[a]s shown in FIG. 3, wound care bandage 10 comprises a thin, flexible wound dressing member 20, shown in FIG. 2." See wound contacting surface 22 of the member 20 shown in FIGS. 3, 7-11, and 16. See paragraph [0033], second sentence, which states "[w]ound contacting surface 22 or portions thereof contact the wound surface 18 as shown in FIG. 7." See holes 36 shown in 2, 5, 7, 8, 10, 11, 13, and 14. See paragraph [0036], first sentence which states "[t]hrough holes 36 are provided in member 20 for communication between the channels 28, 30 of the opposite surface 24 with the channels 32, 34

of the wound contacting surface 22."), **a port to be attached to a vacuum source** (See the vacuum/irrigation port 26 shown in FIGS. 2, 3, and 5. See the port 86 shown in FIG. 16. See the multiple ports 70 shown in FIGS. 12 and 15.), **a plurality of channels extending between the holes and the port** (See channels 28 shown in FIGS. 2, 4, 5, 7, and 9 and channels 32 shown in FIGS. 3, 5, 7, and 14. See paragraph [0033], third sentence, where it is stated in part "opposite surface 24 includes a central vacuum/irrigation port 26 and plurality of channels 28 extending radially away from port 26." See paragraph [0034], first sentence, wherein it is stated "[w]ound contacting surface 22 includes a plurality of channels 32 which radiate outwardly from the center of member 20 similar to channels 28 of the opposite surface."), **and spacers coupled to the wound contacting surface** (See spacers 46 shown in FIGS. 8 and 9. See ridges 50 shown in FIGS. 10 and 11. See ridges 54 shown in FIGS. 13 and 14. See paragraph [0035], third sentence, where it is stated "[e]ach channel 32, 34 of wound contacting surface 22 opens toward the wound surface 18 and includes outer edges 42 which contact the wound surface 18 or which act as spacers to provide space between the member 20 and the wound surface." See paragraph [0039], last sentence, where it is stated "[a]s illustrated by channels 32, 34 of wound contacting surface 22, spacers 46, or ridges 50, it is within the scope of this disclosure to include other structures which acts as spacers to create open spaces 40 between the wound surface 18 and the member 20 when member 20 is placed on the wound surface 18 to distribute suction and irrigation generally uniformly throughout the wound 16."), **wherein the spacers and the wound contacting surface are made from the same material** (See sectional view of the member 20 showing the member 20 and the spacers 46, 50, 54 having the same cross-hatching, as shown in FIGS. 9, 11, and 14),

positioning the member so that at least a portion of the member is inside the open wound having at least some of the spacers resting against the wound surface to space the wound contacting surface of the member apart from the wound surface (See FIG. 7. As noted above, see paragraph [0035], third sentence. See paragraph [0038], second sentence,

where it is stated "[s]pacers 46 protrude outwardly from wound contacting surface 22 to contact wound surface 18." As noted above, see the last sentence of paragraph [0039].), **and**

providing a cover over the member to define a space above the wound surface in which a vacuum is formed when the port is connected to a vacuum source (See cover 62 shown in FIGS. 1, 3, 7,and 16. See paragraph [0042], second and third sentences, where it is stated "[a] sealing film 62 of the bandage 10 is placed over packing 58. Film 62 is provided to cover the entire wound 16 and to extend across and attach to the patient's healthy skin 60, as shown in FIGS. 1 and 7.")

38. A method of treating an open wound having a wound surface located below healthy skin surrounding the open wound (As noted above, see wound care bandage 10 for use with a vacuum source 12 and an irrigation source 14, as shown in FIG. 1. See wound dressing member 20 shown in FIGS. 2-16. See wound 16 shown in FIG. 3. See paragraph [0030], first sentence which states "[b]andage 10 promotes the healing of a large wound 16 (shown in FIGS. 3 and 7) by providing vacuum therapy to the wound 16 to promote blood flow and remove exudates from a wound surface 18 of the wound 16 and by providing for irrigation of the wound 16 with fluids such as saline, for example."), **the method comprising:**

positioning a relatively thin and flexible member so that at least a portion of the member is inside the open wound (See wound dressing member 20 shown in FIGS. 2-16. See paragraph [0031], first sentence which states "[a]s shown in FIG. 3, wound care bandage 10 comprises a thin, flexible wound dressing member 20, shown in FIG. 2." See wound contacting surface 22 of the member 20 shown in FIGS. 3, 7-11, and 16.), **the member having a wound facing surface with holes in the wound facing surface located inside the open wound below the healthy skin surrounding the open wound** (See paragraph [0033], second sentence, which states "[w]ound contacting surface 22 or portions thereof contact the wound surface 18 as shown in FIG. 7." See holes 36 shown in 2, 5, 7, 8, 10, 11, 13, and 14. See paragraph [0036], first

sentence which states "[t]hrough holes 36 are provided in member 20 for communication between the channels 28, 30 of the opposite surface 24 with the channels 32, 34 of the wound contacting surface 22."), **the member also having a single port and passageways connecting each of the holes to the port** (See the vacuum/irrigation port 26 shown in FIGS. 2, 3, and 5. See the port 86 shown in FIG. 16. See channels 28 shown in FIGS. 2, 4, 5, 7, and 9 and channels 32 shown in FIGS. 3, 5, 7, and 14. See paragraph [0033], third sentence, where it is stated in part "opposite surface 24 includes a central vacuum/irrigation port 26 and plurality of channels 28 extending radially away from port 26." See paragraph [0034], first sentence, wherein it is stated "[w]ound contacting surface 22 includes a plurality of channels 32 which radiate outwardly from the center of member 20 similar to channels 28 of the opposite surface."),

spacing the wound facing surface of the member apart from the wound surface to define a space between the wound surface and the wound facing surface of the member (See paragraph [0035], third sentence, where it is stated "[e]ach channel 32, 34 of wound contacting surface 22 opens toward the wound surface 18 and includes outer edges 42 which contact the wound surface 18 or which act as spacers to provide space between the member 20 and the wound surface." See paragraph [0039], last sentence, where it is stated "[a]s illustrated by channels 32, 34 of wound contacting surface 22, spacers 46, or ridges 50, it is within the scope of this disclosure to include other structures which acts as spacers to create open spaces 40 between the wound surface 18 and the member 20 when member 20 is placed on the wound surface 18 to distribute suction and irrigation generally uniformly throughout the wound 16."),

covering the wound and the member with a film (See cover 62 shown in FIGS. 1, 3, 7,and 16. See paragraph [0042], second and third sentences, where it is stated "[a] sealing film 62 of the bandage 10 is placed over packing 58. Film 62 is provided to cover the entire wound 16 and to extend across and attach to the patient's healthy skin 60, as shown in FIGS. 1 and 7."),

sealing the film to healthy skin surrounding the wound to create a sealed environment between the film and the wound surface (As noted above, see cover 62 shown in FIGS. 1 and 16. See also the second and third sentences of paragraph [0042].),

coupling the port of the member to a vacuum source (See FIG. 1. See paragraph [0034], first sentence, where it is stated "[v]acuum/irrigation tube 13 is provided coupled to the port."),

creating a negative pressure in the space between the wound and the surface of the member (See paragraph [0030], first sentence, where it is stated "[b]andage 30 promotes the healing of a large wound 16 (shown in FIGS. 3 and 7) by providing vacuum therapy to the wound 16 to promote blood flow and remove exudates from a wound surface 18 of the wound 16 . . . ." See paragraph [0037], last sentence, where it is stated "[o]pen spaces 40 allow vacuum source 12 to establish a generally uniformly distributed vacuum therapy to draw exudates from the wound 16 into the channels 32, 34 of wound contacting surface 22." See paragraph [0039], fourth sentence, where it is stated "[r]idges 50 . . . provide open spaces 40 between wound surface 18 and member 20 to establish a generally uniform vacuum across the wound surface 18."),

coupling the port of the member to an irrigation source (See FIG. 1. See paragraph [0033], fifth sentence, where it is stated "[p]ort 26, as shown in FIG. 5, includes a shallow cone 64 in order to induce fluids dispensed through a vacuum/irrigation tube 13 from the vacuum and irrigation sources 12, 14 to flow evenly into channels 28." As noted above, see the first sentence of paragraph [0034]. See paragraph [0043], second sentence, where it is stated "[i]n use, irrigation source 14 delivers liquid through tube 13 to port 26."), **and**

irrigating the wound surface by sending an irrigation liquid from the irrigation source through the member to the wound surface (As noted above, see FIG. 1. See paragraph [0033], fifth sentence, where it is stated "[p]ort 26, as shown in FIG. 5, includes a shallow cone 64 in order to induce fluids dispensed through a vacuum/irrigation tube 13 from the

vacuum and irrigation sources 12, 14 to flow evenly into channels 28." As noted above, see the first sentence of paragraph [0034]. See paragraph [0043], second sentence, where it is stated "[i]n use, irrigation source 14 delivers liquid through tube 13 to port 26.").

40. A method of treating a wound having a wound surface (As noted above, see wound care bandage 10 for use with a vacuum source 12 and an irrigation source 14, as shown in FIG. 1. See wound dressing member 20 shown in FIGS. 2-16. See wound 16 shown in FIG. 3. See paragraph [0030], first sentence which states "[b]andage 10 promotes the healing of a large wound 16 (shown in FIGS. 3 and 7) by providing vacuum therapy to the wound 16 to promote blood flow and remove exudates from a wound surface 18 of the wound 16 and by providing for irrigation of the wound 16 with fluids such as saline, for example."), **the method comprising:**

providing a relatively thin and flexible member having a wound contacting surface with holes in the wound contacting surface (See wound dressing member 20 shown in FIGS. 2-16. See paragraph [0031], first sentence which states "[a]s shown in FIG. 3, wound care bandage 10 comprises a thin, flexible wound dressing member 20, shown in FIG. 2." See wound contacting surface 22 of the member 20 shown in FIGS. 3, 7-11, and 16. See paragraph [0033], second sentence, which states "[w]ound contacting surface 22 or portions thereof contact the wound surface 18 as shown in FIG. 7." See holes 36 shown in 2, 5, 7, 8, 10, 11, 13, and 14. See paragraph [0036], first sentence which states "[t]hrough holes 36 are provided in member 20 for communication between the channels 28, 30 of the opposite surface 24 with the channels 32, 34 of the wound contacting surface 22."), **a port to be attached to a vacuum source** See the vacuum/irrigation port 26 shown in FIGS. 2, 3, and 5. See the port 86 shown in FIG. 16. See the multiple ports 70 shown in FIGS. 12 and 15.), **a plurality of channels extending between the holes and the port** (See channels 28 shown in FIGS. 2, 4, 5, 7, and 9 and channels 32 shown in FIGS. 3, 5, 7, and 14. See paragraph [0033], third sentence, where it is stated in part "opposite

surface 24 includes a central vacuum/irrigation port 26 and plurality of channels 28 extending radially away from port 26." See paragraph [0034], first sentence, wherein it is stated "[w]ound contacting surface 22 includes a plurality of channels 32 which radiate outwardly from the center of member 20 similar to channels 28 of the opposite surface."), **and spacers coupled to the wound contacting surface** (See spacers 46 shown in FIGS. 8 and 9. See ridges 50 shown in FIGS. 10 and 11. See ridges 54 shown in FIGS. 13 and 14. See paragraph [0035], third sentence, where it is stated "[e]ach channel 32, 34 of wound contacting surface 22 opens toward the wound surface 18 and includes outer edges 42 which contact the wound surface 18 or which act as spacers to provide space between the member 20 and the wound surface." See paragraph [0039], last sentence, where it is stated "[a]s illustrated by channels 32, 34 of wound contacting surface 22, spacers 46, or ridges 50, it is within the scope of this disclosure to include other structures which acts as spacers to create open spaces 40 between the wound surface 18 and the member 20 when member 20 is placed on the wound surface 18 to distribute suction and irrigation generally uniformly throughout the wound 16."), **wherein the spacers and the wound contacting surface are made from the same material** (See sectional view of the member 20 showing the member 20 and the spacers 46, 50, 54 having the same cross-hatching, as shown in FIGS. 9, 11, and 14),

positioning the member so that at least some of the spacers rest against the wound surface to space the wound contacting surface of the member apart from the wound surface (See FIG. 7. As noted above, see paragraph [0035], third sentence. See paragraph [0038], second sentence, where it is stated "[s]pacers 46 protrude outwardly from wound contacting surface 22 to contact wound surface 18." As noted above, see the last sentence of paragraph [0039].), **and**

providing a cover over the member to define a space above the wound surface in which a vacuum is formed when the port is connected to a vacuum source (See cover 62 shown in FIGS. 1, 3, 7,and 16. See paragraph [0042], second and third sentences,

where it is stated "[a] sealing film 62 of the bandage 10 is placed over packing 58. Film 62 is provided to cover the entire wound 16 and to extend across and attach to the patient's healthy skin 60, as shown in FIGS. 1 and 7.").

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following two grounds of rejection are presented for review:

(1) the rejection of claims 32 and 40 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,762,640 to Kajiwara (hereinafter "Kajiwara").

(2) the rejection of claim 38 under § 103(a) as being unpatentable over U.S. Patent No. 5,549,584 to Gross (hereinafter "Gross") in view of U.S. Patent No. 5,735,833 to Olson (hereinafter "Olson").

ARGUMENT

I. THE BOARD IS URGED TO REVERSE THE FIRST GROUND OF REJECTION

The claims within the first ground of rejection will be separately argued in the following groups:

Group A – claim 32; and

Group B – claim 40.

35 U.S.C. § 102 ANTICIPATION

In accordance with longstanding precedent construing 35 U.S.C. § 102, anticipation of a claim requires a showing that a single prior art reference discloses each and every element and limitation of the claim. See, e.g., *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 20, 57 U.S.P.Q. 2d 1057 (Fed. Cir. 2000); *Electro Medical Systems, S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1052, 32 U.S.P.Q.2d 1017 (Fed. Cir. 1994); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001

(Fed. Cir. 1991); *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1457, 221 USPQ 481, 485 (Fed. Cir. 1984); *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986); *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1571 (Fed. Cir. 1986) ("The corollary of that rule is that absence from the reference of any claimed element negates anticipation."). The Federal Circuit Court of Appeals strictly construes the requirement for a showing of anticipation under 35 U. S. C. § 102:

> "[A]n invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim. The identical invention must be shown in as complete detail as is contained in the patent claim."
>
> *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) (citations omitted).

Furthermore, anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). Thus, a reference does not anticipate a claim if the claim contains any limitation that is neither literally nor inherently present in that reference.

THE EXAMINER'S POSITION

The Examiner takes the position that "Kajiwara teaches . . . providing a relatively thin, and flexible member (1) having a wound contacting surface with holes (2) in the wound contacting surface, a port (6) to be attached to a vacuum source and a plurality of channels (4) extending between the holes (2) and the port (6), and spacers (3) coupled to the wound contacting surface." The Examiner further takes the position that Kajiwara teaches "positioning the member (1) so that at least a portion of the member (1) is inside the open wound . . . and providing a cover over the member (1) to define a space above the wound surface in which a

vacuum is formed when the port (6) is connected to a vacuum source (abstract; col. 3, lines 1-17.)

APPLICATION OF THE LAW

A. Claim 32 is not anticipated by Kajiwara.

Independent claim 32 of the present application is patentable over Kajiwara because Kajiwara does not disclose or suggest every limitation within claim 32.

In particular, claim 32 recites "providing a relatively thin and flexible member." Kajiwara does not disclose or suggest any such "flexible member." Rather, Kajiwara discloses a disk 1, as shown in FIGS. 2A, 2B, and 5. As noted at col. 3, ll. 56-58 of Kajiwara, "[t]he disk 1 which is a single member remains highly rigid without resorting to a frame."

The Examiner takes the position that "[r]egarding the terminology, "thin and flexible", these are relative terms as stainless steel and the like can be flexed when sufficient force is applied. See page 3 of the April 17, 2008 Final Office Action. The Appellants generally agree that the term "flexible" can be a relative term. For example, given enough force, every structure is able to be flexed at least at the microscopic or cellular level. However, such structures are not necessarily "flexible." Such an interpretation otherwise is neither reasonable nor is it understood by one of ordinary skill in the art to be an ordinary use of the term. In particular, the broadest reasonable interpretation doctrine requires claim terms to be interpreted in light of the words in their ordinary usage while also taking into account the use of the terms within the Appellant's specification. In particular, the MPEP § 2111 states the following:

> Since it would be unreasonable for the PTO to ignore any interpretive guidance afforded by the Appellant's written description, either phrasing connotes the same notion: as an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description

contained in the Appellant's specification. *In re Morris*, 1054-1055.

By asserting that the "highly rigid" disk 1 of Kajiwara anticipates the "flexible member" recited in Appellant's claim 32, the Examiner is thereby construing the term "flexible" to include something which is "highly rigid." Such an interpretation of the term "flexible" is unreasonable. Under any ordinary, practical use of the term flexible as understood by one of ordinary skill in the art, a flexible member cannot also be considered to be highly rigid. In fact, the ordinary meaning of these terms is completely opposite one another.

Furthermore, in light of the Appellant's specification, the term "flexible" also cannot be construed to include something which is "highly rigid." For example, FIG. 7 of the present application specifically shows the flexible member 20 within a wound 16 and illustrates the flexible nature of the member 20 to conformingly rest against the wound surface of the patient's wound. Further, the specification of the present application states that "[m]ember 20 is made of a medical grade silicone or other type of elastomer which is pliable." See paragraph [0031] of the present application. It is also stated that "[i]llustratively, member 20 is made from a silicone of a Durometer 50A which is flexible with a thickness of 0.0800 inches." See paragraph [0032] of the present application. These portions of the specification clearly align with the ordinary usage of the term flexible as understood by one of ordinary skill in the art to exclude something which is "highly rigid."

As such, the "highly rigid" disk 1 of Kajiwara does not anticipate the claimed "flexible member" recited in claim 32. In other words, Kajiwara does not disclose or suggest any "flexible member."

Claim 32 further recites "positioning the member so that at least a portion of the member is inside the open wound having at least some of the spacers resting against the wound surface to space the wound contacting surface of the member apart from the wound surface." The Examiner states that "[i]t is noted that the adhesive spacer layer (3) directly contacts the wound during use." Respectfully, Appellants disagree with this statement. First of all, no

portion of the effusion fluid sucking device of Kajiwara is positioned inside any open wound. Rather, the device of Kajiwara is provided for "sucking and sampling an effusion fluid from an organism." See col. 1, ll. 1-3 of Kajiwara. In particular, Kajiwara references an article within the NEC Technical Report, vol. 48, No. 3, 4, (1995) titled "Portable Blood Glucose Monitoring System", the translated abstract of which is attached to the Exhibit section of the Appeal Brief and which states, in part, the following:

> The NEC has developed a portable blood glucose monitoring system using the suction effusion fluids (SEF) as a sample. The SEF is transcutaneously collected by sucking corneous layer stripped skin.

By definition, a "transcutaneous" process is a process that is conducted without breaking the patient's skin and certainly without forming any wound in the patient's skin. Accordingly, the SEF collection process referenced by Kajiwara does not break the patient's skin, does not form any wound in the patient's skin, and is not used to treat an existing patient wound. Accordingly, Kajiwara does not disclose or suggest "positioning the member so that at least a portion of the member is inside the open wound" because Kajiwara does not disclose the use of the effusion device with a wound and clearly does not disclose positioning the effusion device within any wound.

Further, Kajiwara does not disclose or suggest "positioning the member so that . . . at least some of the spacers [rest] against the wound surface." Examiner asserts that the annular projection 3 of the disk 1 operates as the claimed "spacers." However, such spacers are clearly not positioned within any wound for two reasons. First of all, as noted above, the effusion device of Kajiwara is not used with any patient wound. Secondly, even if one were to assume, for argument's sake, that the effusion device of Kajiwara is used with a patient wound (a position Appellants dispute), the projection 3 of the device would still not be positioned to rest against any such wound surface because the projection 3 must form a vacuum seal against healthy skin of the patient. For example, Kajiwara states that "[w]hen the end of the cell around the cavity 5 is brought into contact with the skin, the projection 3 tightly contacts the skin and thereby enhances

air-tightness." See col. 3, ll. 20-23 of Kajiwara. Accordingly, while the disk 1 of Kajiwara may contact the patient's skin, as discussed at col. 4, ll. 28-30 of Kajiwara, the annular projection 3 of the disk 1 does not rest against any *wound surface*. Rather, the projection 3 "tightly contacts the skin and thereby enhances air-tightness." See col. 3, ll. 22-23 of Kajiwara. Accordingly, the projection 3 of Kajiwara must engage healthy skin of the patient in order to form such an air-tight seal. As such, for the reasons discussed above, Kajiwara does not disclose or suggest "spacers resting against the wound surface" as is recited in claim 32.

Further, Kajiwara does not disclose or suggest "positioning the member . . . to space the wound contacting surface of the member apart from the wound surface" as is recited in claim 32. In particular, Kajiwara specifically discloses that the disk 1 contacts the patient's skin as noted at col. 4, ll. 27-32 as follows:

> In any of the specific patterns shown in FIGS. 3 and 4, the surface of the disk 1 to contact the skin, except for the holes 2, may be formed with irregular grooves such that it has a surface roughness of several microns. Generally, the skin is extremely soft and deforms in such a manner as to stop the holes 2 in the event of evacuation. The above irregular grooves of the disk 1 will surely guide the fluid into the holes 2 despite the deformation of the skin.

Accordingly, Kajiwara teaches that the bottom surface of the disk 1 specifically contacts and engages the patient's skin during use and is not spaced-apart from any wound surface.

As noted above, it is the spacers 46, 50, 54, and the edges of channels 32, 34 of the member 20 disclosed in the present application which operate to create open spaces 40 between the wound surface 18 and the member 20 to distribute suction and irrigation generally uniformly throughout the wound 16. See paragraph [0039] of the present application. In particular, the present application teaches that "the vacuum suction draws exudates into the open spaces and up through the holes 36." See paragraph [0044] of the present application. Accordingly, the present application teaches that the spacers of the wound member operate to maintain open spaces 40 between the bottom, wound contacting surface of the member 20 and

the wound surface 18 during operation of the vacuum source to draw wound exudates from the wound 18 and through the member 20. Kajiwara, on the other hand, specifically teaches that the bottom of the disk 1 contacts the patient's skin during use of the effusion device. As such, Kajiwara specifically does not disclose or suggest "positioning the member so that at least a portion of the member is inside the open wound having at least some of the spacers resting against the wound surface to space the wound contacting surface of the member apart from the wound surface" as is recited in the invention of claim 32 of the present application. For at least this additional reason, Kajiwara does not anticipate the method of wound treatment recited in claim 32.

Claim 32 further recites "providing a cover over the member to define a space above the wound surface in which a vacuum is formed when the port is connected to a vacuum source." The Examiner asserts in annotated figure 2A of the April 17, 2008 Final Official Action that the structure surrounding the suction port 13 operates as such a "cover." Respectfully, Appellants disagree with such an assertion. In particular, claim 32 specifically requires that the claimed "cover" must "define a space above the wound surface in which a vacuum is formed." The structure surrounding the suction port 13 of Kajiwara may operate to communicate a negative pressure from a vacuum source to the disk 1, however, such a structure does not define a space above the wound surface in which a vacuum is formed.

Furthermore, it is clear from reading Kajiwara that the space in which such a vacuum is formed is located between the disk 1 and the patient's skin. As noted above, Kajiwara states that "[w]hen the end of the cell around the cavity 5 is brought into contact with the skin 1, the projection 3 tightly contacts the skin and thereby enhances air-tightness. As a result, the device is free from the leak of air discussed in relation to the prior art device." See col. 3, ll. 20-25 of Kajiwara. See also, col. 5, ll. 41-43 of Kajiwara where it is stated that "[a]n annular projection extending along the edge of the first disk insures tight contact between the disk and the skin, thereby obviating the leak of the fluid." Accordingly, it is the disk 1 with the annular

projection 3 which defines the space above the patient's skin in which a vacuum is formed. Therefore, assuming for argument purposes only that the annular ring 3 and at least a portion of the main body of the disk 1 cooperate to "define a space above the wound surface in which a vacuum is formed," the disk 1 and annular ring 3 certainly do not also provide "a cover over the member." In other words, the space of Kajiwara in which a vacuum is formed does not include any "relatively thin and flexible member having . . . spacers" therein. As such, Kajiwara does not disclose or suggest "providing a cover over the member to define a space above the wound surface in which a vacuum is formed when the port is connected to a vacuum source" in addition to "positioning the member so that at least a portion of the member is inside the open wound having at least some of the spacers resting against the wound surface to space the wound contacting surface of the member apart from the wound surface."

For at least this other additional reason, Kajiwara does not anticipate the method of wound treatment recited in claim 32.

Based on the foregoing, it is respectfully requested that the Board find that independent claim 32 is patentable for at least the reason that Kajiwara does not disclose or suggest all of the limitations recited in claim 32.

B. Claim 40 is not anticipated by Kajiwara.

Independent claim 40 of the present application is patentable over Kajiwara because Kajiwara does not disclose or suggest every limitation within claim 40.

In particular, claim 40 recites "providing a relatively thin and flexible member." Kajiwara does not disclose or suggest any such "flexible member." Rather, Kajiwara discloses a disk 1, as shown in FIGS. 2A, 2B, and 5. As noted at col. 3, ll. 56-58 of Kajiwara, "[t]he disk 1 which is a single member remains highly rigid without resorting to a frame."

The Examiner takes the position that "[r]egarding the terminology, "thin and flexible", these are relative terms as stainless steel and the like can be flexed when sufficient

force is applied. See page 3 of the April 17, 2008 Final Office Action. The Appellants generally agree that the term "flexible" can be a relative term. For example, given enough force, every structure is able to be flexed at least at the microscopic or cellular level. However, such structures are not necessarily "flexible." Such an interpretation otherwise is neither reasonable nor is it understood by one of ordinary skill in the art to be an ordinary use of the term. In particular, the broadest reasonable interpretation doctrine requires claim terms to be interpreted in light of the words in their ordinary usage while also taking into account the use of the terms within the Appellant's specification. In particular, the MPEP § 2111 states the following:

> Since it would be unreasonable for the PTO to ignore any interpretive guidance afforded by the Appellant's written description, either phrasing connotes the same notion: as an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the Appellant's specification. *In re Morris*, 1054-1055.

By asserting that the "highly rigid" disk 1 of Kajiwara anticipates the "flexible member" recited in Appellant's claim 40, the Examiner is thereby construing the term "flexible" to include something which is "highly rigid." Such an interpretation of the term "flexible" is unreasonable. Under any ordinary, practical use of the term flexible as understood by one of ordinary skill in the art, a flexible member cannot also be considered to be highly rigid. In fact, the ordinary meaning of these terms is completely opposite one another.

Furthermore, in light of the Appellant's specification, the term "flexible" also cannot be construed to include something which is "highly rigid." For example, FIG. 7 of the present application specifically shows the flexible member 20 within a wound 16 and illustrates the flexible nature of the member 20 to conformingly rest against the wound surface of the patient's wound. Further, the specification of the present application states that "[m]ember 20 is made of a medical grade silicone or other type of elastomer which is pliable." See paragraph

[0031] of the present application. It is also stated that "[i]llustratively, member 20 is made from a silicone of a Durometer 50A which is flexible with a thickness of 0.0800 inches." See paragraph [0032] of the present application. These portions of the specification clearly align with the ordinary usage of the term flexible as understood by one of ordinary skill in the art to exclude something which is "highly rigid."

As such, the "highly rigid" disk 1 of Kajiwara does not anticipate the claimed "flexible member" recited in claim 40. In other words, Kajiwara does not disclose or suggest any "flexible member."

Claim 40 further recites "positioning the member so that at least some of the spacers rest against the wound surface to space the wound contacting surface of the member apart from the wound surface." The Examiner states that "[i]t is noted that the adhesive spacer layer (3) directly contacts the wound during use." Respectfully, Appellants disagree with this statement. First of all, no portion of the effusion fluid sucking device of Kajiwara is positioned inside any open wound. Rather, the device of Kajiwara is provided for "sucking and sampling an effusion fluid from an organism." See col. 1, ll. 1-3 of Kajiwara. In particular, Kajiwara references an article within the NEC Technical Report, vol. 48, No. 3, 4, (1995) titled "Portable Blood Glucose Monitoring System", the abstract of which is attached to the Evidence Exhibit section of this Appeal Brief which states, in part, the following:

> The NEC has developed a portable blood glucose monitoring system using the suction effusion fluids (SEF) as a sample. The SEF is transcutaneously collected by sucking corneous layer stripped skin.

By definition, a "transcutaneous" process is a process that is conducted without breaking the patient's skin and certainly without forming any wound in the patient's skin. Accordingly, the SEF collection process referenced by Kajiwara does not break the patient's skin, does not form any wound in the patient's skin, and is not used to treat an existing patient wound. Accordingly, Kajiwara does not disclose or suggest any spacers which "rest against the

wound surface", as is recited in claim 40, because Kajiwara does not disclose the use of the effusion device with a wound.

Secondly, even if one were to assume, for argument's sake, that the effusion device of Kajiwara is used with a patient wound (a position Appellants dispute), the projection 3 of the device would still not be positioned to rest against any such wound surface because the projection 3 must form a vacuum seal against healthy skin of the patient. For example, Kajiwara states that "[w]hen the end of the cell around the cavity 5 is brought into contact with the skin, the projection 3 tightly contacts the skin and thereby enhances air-tightness." See col. 3, ll. 20-23 of Kajiwara. Accordingly, while the disk 1 of Kajiwara may contact the patient's skin, as discussed at col. 4, ll. 28-30 of Kajiwara, the annular projection 3 of the disk 1 does not rest against any *wound surface*. Rather, the projection 3 "tightly contacts the skin and thereby enhances air-tightness." See col. 3, ll. 22-23 of Kajiwara. Accordingly, the projection 3 of Kajiwara must engage healthy skin of the patient in order to form such an air-tight seal. As such, for the reasons discussed above, Kajiwara does not disclose or suggest "spacers [resting] against the wound surface" as is recited in claim 40.

Further, Kajiwara does not disclose or suggest "positioning the member . . . to space the wound contacting surface of the member apart from the wound surface" as is recited in claim 40. In particular, Kajiwara specifically discloses that the disk 1 contacts the patient's skin as noted at col. 4, ll. 27-32 as follows:

> In any of the specific patterns shown in FIGS. 3 and 4, the surface of the disk 1 to contact the skin, except for the holes 2, may be formed with irregular grooves such that it has a surface roughness of several microns. Generally, the skin is extremely soft and deforms in such a manner as to stop the holes 2 in the event of evacuation. The above irregular grooves of the disk 1 will surely guide the fluid into the holes 2 despite the deformation of the skin.

Accordingly, Kajiwara teaches that the bottom surface of the disk 1 specifically contacts and engages the patient's skin during use and is not spaced-apart from any wound surface.

As noted above, it is the spacers 46, 50, 54, and the edges of channels 32, 34 of the member 20 disclosed in the present application which operate to create open spaces 40 between the wound surface 18 and the member 20 to distribute suction and irrigation generally uniformly throughout the wound 16. See paragraph [0039] of the present application. In particular, the present application teaches that "the vacuum suction draws exudates into the open spaces and up through the holes 36." See paragraph [0044] of the present application. Accordingly, the present application teaches that the spacers of the wound member operate to maintain open spaces 40 between the bottom, wound contacting surface of the member 20 and the wound surface 18 during operation of the vacuum source to draw wound exudates from the wound 18 and through the member 20. Kajiwara, on the other hand, specifically teaches that the bottom of the disk 1 contacts the patient's skin during use of the effusion device. As such, Kajiwara specifically does not disclose or suggest "positioning the member so that at least a portion of the member is inside the open wound having at least some of the spacers resting against the wound surface to space the wound contacting surface of the member apart from the wound surface" as is recited in the invention of claim 40 of the present application. For at least this additional reason, Kajiwara does not anticipate the method of wound treatment recited in claim 40.

Claim 40 further recites "providing a cover over the member to define a space above the wound surface in which a vacuum is formed when the port is connected to a vacuum source." The Examiner asserts in annotated figure 2A of the April 17, 2008 Final Official Action that the structure surrounding the suction port 13 operates as such a "cover." Respectfully, Appellants disagree with such an assertion. In particular, claim 40 specifically requires that the claimed "cover" must "define a space above the wound surface in which a vacuum is formed." The structure surrounding the suction port 13 of Kajiwara may operate to communicate a negative pressure from a vacuum source to the disk 1, however, such a structure does not define a space above the wound surface in which a vacuum is formed.

Furthermore, it is clear from reading Kajiwara that the space in which such a vacuum is formed is located between the disk 1 and the patient's skin. As noted above, Kajiwara states that "[w]hen the end of the cell around the cavity 5 is brought into contact with the skin 1, the projection 3 tightly contacts the skin and thereby enhances air-tightness. As a result, the device is free from the leak of air discussed in relation to the prior art device." See col. 3, ll. 20-25 of Kajiwara. See also, col. 5, ll. 41-43 of Kajiwara where it is stated that "[a]n annular projection extending along the edge of the first disk insures tight contact between the disk and the skin, thereby obviating the leak of the fluid." Accordingly, it is the disk 1 with the annular projection 3 which defines the space above the patient's skin in which a vacuum is formed. Therefore, assuming for argument purposes only that the annular ring 3 and at least a portion of the main body of the disk 1 cooperate to "define a space above the wound surface in which a vacuum is formed," the disk 1 and annular ring 3 certainly do not also provide "a cover over the member." In other words, the space of Kajiwara in which a vacuum is formed does not include any "relatively thin and flexible member having . . . spacers" therein. As such, Kajiwara does not disclose or suggest "providing a cover over the member to define a space above the wound surface in which a vacuum is formed when the port is connected to a vacuum source" in addition to "positioning the member so that at least a portion of the member is inside the open wound having at least some of the spacers resting against the wound surface to space the wound contacting surface of the member apart from the wound surface."

For at least this other additional reason, Kajiwara does not anticipate the method of wound treatment recited in claim 40.

Based on the foregoing, it is respectfully requested that the Board find that independent claim 40 is patentable for at least the reason that Kajiwara does not disclose or suggest all of the limitations recited in claim 40.

II. THE BOARD IS URGED TO REVERSE THE SECOND GROUND OF REJECTION

Independent claim 38 within the second ground of rejection is patentable over Gross and Olson because the combination of Gross and Olson does not arrive at the invention recited in claim 38. In other words, the resulting structure of the combined teachings of Gross and Olson would not read on independent claim 38. Thus claim 38 is patentably distinguishable over the Gross and Olson combination.

35 U. S. C. § 103 OBVIOUSNESS

The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138, 227 USPQ 543, 548 (Fed. Cir. 1985), citing In re Piasecki, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). That knowledge cannot come from the Appellant's invention itself. In re Oetiker, 977 F.2d at 1447, citing Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); In re Geiger, 815 F.2d 686, 687, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1147, 227 USPQ 543, 551 (Fed. Cir. 1985). Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

> "[V]irtually all [inventions] are combinations of old elements. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698, 218 U.S.P.Q. 865, 870 (Fed. Cir. 1983); *see also Richdel, Inc. v.*

> *Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 U.S.P.Q. 8, 12 (Fed.Cir.1983) ("Most, if not all, inventions are combinations and mostly of old elements."). An examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability."
>
> In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998),

citing Sensonics, Inc. v. Aerosonic Corp., 81 F.3d 1566, 1570, 38 USPQ.2d 1551, 1554 (Fed. Cir. 1996).

The Federal Circuit has identified three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. In re Rouffet, 149 F.3d at 1357. The factual inquiry whether to combine references must be thorough and searching. In re Lee, 61 USPQ.2d at 1533. Particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). The examiner must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious. In re Rouffet, 149 F.3d at 1359, 47 USPQ2d at 1459.

> "It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to '[use] that which the inventor taught against its teacher.'" W. L. Gore v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Thus the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion."
>
> In re Lee, 61 USPQ2d at 1435.

Further, in a recent decision, the United States Supreme Court clarified the test for obviousness. See KSR Int'l. Co. v. Teleflex, Inc. et al., 127 S.Ct. 1727 (2007). The Supreme Court in *KSR* reaffirmed that certain principles govern the analysis of obviousness. One such principle is that an examiner "in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements [must] identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." See Memorandum from Margaret A. Focarino, Deputy Commissioner for Patent Operations to Technology Center Directors (May 3, 2007) (hereinafter "Forcarino Memo") (quoting KSR, 127 S.Ct. at 1741). Another principle the *KSR* court emphasized is the need for the examiner to engage in an explicit analysis of obviousness; as the Court stated: "rejections on obviousness grounds *cannot be sustained by mere conclusory statements*; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 127 S.Ct. at 1741 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

THE EXAMINER'S POSITION

In making this rejection, the Examiner stated that "Gross does not teach the step of irrigating a wound through that device" and that "Olson teaches irrigation ports (52, 64) that deliver irrigating fluids to a wound site." The Examiner the directed us to FIG. 5 of Olson and further stated that "[a]dding these ports on Gross' cover (18) adjacent to Gross' port (28) would result in fluid passing through holes before irrigating the wound." See page 7 of the April 17, 2008 Final Office Action.

Further, in response to Appellant's previously arguments, the Examiner further stated the following within the Response to Arguments section of the Final Official Action:

> Regarding claim 38, Appellants assert that Olson teaches multiple separate ports to accommodate the separate suction and irrigation functions of that device, while the instant invention claims a single port for these functions. This argument is not persuasive because merely making what is know in the art to be separable, integral is not sufficient to patentably distinguish the claimed invention over

the prior art. See *In re Larson,* 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965). MPEP § 2144.04.

Furthermore, this argument is not persuasive because the neck (34) of Olson can be reasonably construes [sic] a single port. Also, Appellants use the transitional phrase "comprising". The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g. *Mars Inc. v. H.J. Heinz Col,* 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended."). MPEP § 2111.03. Appellants' single port does not preclude additional ports.

APPLICATION OF THE LAW

First of all, Appellants continue to disagree with the Examiner's assertion that the neck 34 of Olson can be reasonably construed as a single port. In particular, it is clear that that the neck 34 includes two separate openings 38, 40, as shown in FIG. 2 of Olson and described at col. 3, ll. 3-5 of Olson. Accordingly, the neck 34 is a single structure which *includes* two ports. The neck itself is not "a single port," but a structure which includes two ports. Any structure which includes multiple ports cannot itself be considered as a single port. For example, a sink may include a first port configured to receive a faucet, a second port configured to receive a left handle, and a third port configured to receive a right handle. This sink clearly includes three ports. Under the Examiner's interpretation, however, such a sink would itself be considered a single port. Obviously, such an interpretation is nonsensical and misconstrues the meaning of the term port. Clearly, therefore, Olson discloses a lavage tip having a neck which includes multiple ports.

Secondly, Appellants continue to disagree with the Examiner's assertion that the "single port" recited in claim 38 does not preclude additional portions. In fact, the specific recitation of the "single port" does operate to preclude additional ports. While Appellants agree that an indefinite article "a" or "an" when used with the term "comprising" carries the meaning

of "one or more", it is possible to limit this reading as set forth by the U.S. Court of Appeals for the Federal Circuit which recently held the following:

That "a" or "an" can mean "one or more" is best described as a rule, rather than merely as a presumption or even a convention. The exceptions to this rule are extremely limited: a patentee must "evince[] a clear intent" to limit "a" or "an" to "one."

Baldwin Graphic Systems, Inc. v. Siebert, Inc., 2008 U.S. App. LEXIS 783, 10, citing *KJC Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000).

The court further stated that "[a]n exception to the general rule that 'a' or 'an' means more than one only arises where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rules." *Id.* at 10-11.

Appellants have shown a clear intent to limit the claimed port to 'one' by amending the claim itself to recite "a single port." Appellants have further shown a clear intent to limit the claimed port to 'one' within the prosecution history, namely the response filed August 2, 2007 whereby the claimed "single port" was distinguished from Olson which clearly discloses multiple ports, as well as within the response filed January 28, 2008 where the same arguments stated herein were previously set forth. Accordingly, there is no question that Appellants intend to limit the "thin and flexible member" recited in claim 38 to include only "a single port." Such limitation specifically precludes the use of multiple ports. Appellants have now gone on record three times to reiterate this fact. Accordingly, the "single port" recited in claim 38 does, in fact, operate to preclude additional ports.

Finally, neither Gross nor Olson disclose or suggest "coupling the port of the member to a vacuum source" and "coupling the port of the member to an irrigation source", as is recited in claim 38. In particular, the "single port" of the "thin and flexible member" recited in claim 38 is able to be coupled to both the vacuum source and the irrigation source. Olson discloses a lavage tip 10 having a liquid port 22 and a separate suction port 26, as shown in FIG. 2 of Olson. Olson further discloses a lavage tip 50 having a liquid delivery tube 52, a suction

tube 54, and an oxygen delivery tube 64 as shown in FIG. 5 of Olson. In other words, the lavage tips 10, 50 of Olson clearly include multiple ports which are each coupled to only one source, such as the fluid source 12, the vacuum 14, or the oxygen source (not shown) of Olson. Accordingly, Olson does not disclose a device having a "single port" and clearly does not disclose the steps of coupling such a single port to both a vacuum source and an irrigation source, as recited in claim 38 of the present application. Gross does not make up for this deficiency of Olson. As such, the combination of Gross and Olson does not arrive at the method recited in claim 38.

Finally, Appellants disagree with the Examiner's assertion that claim 38 is "merely making what is known in the art to be separable, integral" and that this is "not sufficient to patentably distinguish the claimed invention over the prior art." Appellants are not "merely making what is known in the art to be separable, integral" but are rather substantially changing the structure and function of the device shown in Olson. For example, taking the separate irrigation and suction openings 38, 40 of Olson and combining them into one singular opening destroys the functionality of the lavage tip 10 completely. In particular, the separate openings 38, 40 of the lavage tip 10 of Olson allow irrigation fluid and negative pressure to be communicated to the lavage tip 10 at the same time. Combining these openings 38, 40, however, into a singular opening will prevent the lavage tip 10 from being able to operate both the fluid source 12 and the vacuum 14 simultaneously. Accordingly, Appellants assert that providing a single port coupled to both an irrigation source and a vacuum source is not equivalent to making what is known in the art to be separable, integral. As such, altering the lavage tips 10, 50 of Olson to exchange the separate openings 38, 40 for a singular port is not an obvious alteration.

Furthermore, it is questionable whether any of the "shorthand" rejection tools laid out in MPEP § 2144.04 should ever be relied upon by any examiner or the Board in making a claim rejection given the following pronouncement from the U.S. Court of Appeals for the

Federal Circuit in the case *In re Ochiai*, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995), the relevant portion of which is reproduced as follows:

> The use of *per se* rules, while undoubtedly less laborious than a searching comparison of the claimed invention – including all its limitations – with the teachings of the prior art, flouts section 103 and the fundamental case law applying it. *Per se* rules that eliminate the need for fact-specific analysis of claims and prior art may be administratively convenient for PTO examiners and the Board. Indeed, they have been sanctioned by the Board as well. **But reliance on *per se* rules of obviousness is legally incorrect and must cease.** Any such administrative convenience is simply inconsistent with section 103, which, according to *Graham*, and its progeny, entitles the Appellant to issuance of an otherwise proper patent unless the PTO establishes that the invention *as claimed* in the application is obvious over the cited prior art, based on specific comparison of that prior art with claim limitations. We once again hold today that our precedents do not establish any *per se* rules of obviousness, just as those precedents themselves expressly declined to create such rules. Any conflicts as may be perceived to exist derive from an impermissible effort to extract *per se* rules from decisions that disavow precisely such extraction. (Emphasis added via bolding; italics in original)

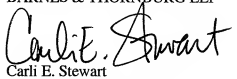
Olson does not have the recited structure of claim 38 (i.e., a single port) and therefore, the rejection of claim 38 as being obviousness is unfounded. In light of the foregoing, Appellant urges the Board to reverse the Examiner's rejection of claim 38 as being unpatentable under 35 U.S.C. § 103(a) over Gross in view of Olson.

SUMMARY CONCLUSIONS

For the above reasons, the 35 U.S.C. § 102 rejection of claims 32 and 40 based on Kajiwara and the 35 U.S.C. § 103 rejection of claim 38 based on Gross in view of Olson are erroneous. The Board is thus urged to reverse those rejections. Such action is respectfully requested.

Respectfully submitted,

BARNES & THORNBURG LLP



Carli E. Stewart
Attorney Reg. No. 51,058

carli.stewart@btlaw.com
Indianapolis, Indiana
317-231-7216

32. A method of treating an open wound having a wound surface located inwardly of healthy skin surrounding the open wound, the method comprising:

providing a relatively thin and flexible member having a wound contacting surface with holes in the wound contacting surface, a port to be attached to a vacuum source, a plurality of channels extending between the holes and the port, and spacers coupled to the wound contacting surface, wherein the spacers and the wound contacting surface are made from the same material,

positioning the member so that at least a portion of the member is inside the open wound having at least some of the spacers resting against the wound surface to space the wound contacting surface of the member apart from the wound surface, and

providing a cover over the member to define a space above the wound surface in which a vacuum is formed when the port is connected to a vacuum source.

38. A method of treating an open wound having a wound surface located below healthy skin surrounding the open wound, the method comprising:

positioning a relatively thin and flexible member so that at least a portion of the member is inside the open wound, the member having a wound facing surface with holes in the wound facing surface located inside the open wound below the healthy skin surrounding the open wound, the member also having a single port and passageways connecting each of the holes to the port,

spacing the wound facing surface of the member apart from the wound surface to define a space between the wound surface and the wound facing surface of the member,

covering the wound and the member with a film,

sealing the film to healthy skin surrounding the wound to create a sealed environment between the film and the wound surface,

coupling the port of the member to a vacuum source,

creating a negative pressure in the space between the wound and the surface of the member,

coupling the port of the member to an irrigation source, and

irrigating the wound surface by sending an irrigation liquid from the irrigation source through the member to the wound surface.

40. A method of treating a wound having a wound surface, the method comprising:

providing a relatively thin and flexible member having a wound contacting surface with holes in the wound contacting surface, a port to be attached to a vacuum source, a plurality of channels extending between the holes and the port, and spacers coupled to the wound contacting surface, wherein the spacers and the wound contacting surface are made from the same material,

positioning the member so that at least some of the spacers rest against the wound surface to space the wound contacting surface of the member apart from the wound surface, and

providing a cover over the member to define a space above the wound surface in which a vacuum is formed when the port is connected to a vacuum source.

EVIDENCE APPENDIX

A translated copy of the abstract of the following article is attached hereto.

"Portable Blood Glucose Monitoring System", NEC Technical Report, vol. 48, No. 3, 4, (1995).

This article is cited as prior art within Kajiwara and is referenced within the specification section of Kajiwara.

06076128/9
06076128 **INSPEC Abstract Number:** A9522-8780B-001, B9511-7510-020
Title: Portable blood glucose monitoring system
Author Kaneyoshi, A.; Iwasaki, H.; Nishida, T.; Murakami, S.; Ito, N.; Saito, A.
Journal: NEC Technical Journal vol.48, no.7 p. 7-13

Publication Date: July 1995 **Country of Publication:** Japan
CODEN: NECGEZ **ISSN:** 0285-4139

Language: Japanese **Document Type:** Journal Paper (JP)
Treatment: Applications (A); Practical (P); Experimental (X)
Abstract: The NEC has developed a portable blood glucose monitoring system using the suction effusion fluids (SEF) as a sample. The SEF is transcutaneously collected by sucking corneous layer stripped skin. The glucose concentration in the SEF shows good correlation with that in serum. This system consists of a main body and a suction apparatus. A rotary valve for collecting a 5 mu l sample, a sensor cell with an ion sensitive field effect transistor (ISFET) glucose sensor, and small low-power pumps have been developed to configure the portable system. This system has been tested with a rabbit, and compared with the glucose concentration in the SEF from the different portion of the same rabbit with manual suction apparatus. The results of these procedures were almost identical. (13 Refs)
Subfile: A B
Descriptors: biological techniques; biosensors; blood; patient monitoring; portable instruments
Identifiers: portable blood glucose monitoring system; NEC; suction effusion fluids; corneous layer stripped skin; glucose concentration; correlation; serum; suction apparatus; rotary valve; sensor cell; ion sensitive field effect transistor; ISFET; glucose sensor; low-power pumps; rabbit
Class Codes: A8780B (Biosensors); A8770E (Patient diagnostic methods and instrumentation); B7510 (Biomedical measurement and imaging); B7230J (Biosensors)

RELATED PROCEEDINGS APPENDIX

None